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| EXAMINER |
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HARTLEY, MICHAEL G

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 12/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/614,490

Applicant(s)

O'FOGHLUDHA, FEARGHUS

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

The amendment filed 10/28/2002 has been entered. Claim 2 has been canceled. Claim 1 has been amended. New claims 5-9 have been added.

Response to Arguments

Any previous rejections that are not reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1 and 3-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Suthanthiran (US 5,163,896), for the reasons set forth in the office action mailed 4/22/2002.

Applicant's arguments filed 10/28/2002 have been fully considered but they are not persuasive.

Applicant asserts that Suthanthiran fails to disclose a nuclide that is a chemically bound constituent of a polymer chain.

However, proper analysis of the claims does not require the presence of a nuclide in the chain of the polymer, as suggested in the arguments, but rather only "at least one nuclide which is activatable by exposure to radiation," see claim 1. The important issue in the interpretation of the claim language herein is the term "activatable," which does not require a radionuclide, but only an atom that can be turned into radionuclide via exposure to radiation. Such atoms include carbon, for example, as is specifically defined

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as such a nuclide in claim 4. Note, the term "activatable" (in a product claim) is analogous to "capable of" which is not a positive recitation in any patentable sense. See *In re Hutchison*, 69 USPQ 138. Thus, since the nuclide may be carbon, the polymer only needs to have carbon in the polymer chain (i.e., note, carbon is activatable into a radioisotope by radiation). Suthanthiran discloses such polymers. For example, Suthanthiran discloses polyamino acids (i.e., polytyrosine), which have a carbon in the polymer chain. Suthanthiran also discloses that the radioactive source may comprise nylon, which is within the scope of claim 4. Since the polymers, as claimed, comprise an "activatable" nuclide, in essence, a non-radioactive polymer is claimed in the claimed integral source. Such a polymer includes nylon (claim 4), which is disclosed by Suthanthiran. Also, the polymers disclosed by Suthanthiran are configured to form a device that would be within the scope of rectangular shaped sources, see figure 1, or at least a radioactive enclosure. Note, the device as a test-device, etc. as claimed are intended use limitations, but such limitations do not specifically limit the product to a certain physical form which is not encompassed by the prior art. The encapsulants include rigid and flexible material, i.e., rubber, titanium, aluminum, etc., see column 7.

Claims 1 and 3-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Park (US 6,152,869), for the reasons set forth in the office action mailed 4/22/2002.

Applicant's arguments filed 10/28/2002 have been fully considered but they are not persuasive.

Again applicant asserts that Park fails to disclose a nuclide that is a chemically bound constituent of a polymer chain.

This is not found persuasive because the claims are not limited to a product which has a radionuclide that is a chemically bound constituent of a polymer chain, but only a "activatable" nuclide, i.e., a non-radioactive atom (or nuclide) which is "capable of" being activated by radiation to yield a radionuclide. Such atoms or nuclide include carbon, as seen by claim 4. Park discloses an integral source which comprises a polymer having carbon in the polymer chain. For example, the source disclosed by Park includes polyurethane, nylon, etc., (column 6, lines 40-43), which is within the scope of the claimed polymers, as set forth in claim 3. Thus, Park discloses an integral source comprising a

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polymer having all the same limitations of the polymer as claimed. The products disclosed by Park include both flexible (e.g., plastic) and rigid (metal) encapsulants, see column 6.

Claims 1 and 3-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Eury (US 5,871,436), for the reasons set forth in the office action mailed 4/22/2002.

Applicant's arguments filed 10/28/2002 have been fully considered but they are not persuasive.

Applicant asserts that Eury fails to disclose a nuclide that is chemically bound constituent of a polymer chain and fails to disclose a nuclide which is activatable by exposure to radiation.

It is noted that the claims are to a product, in which no activation step is relevant, as this would signify a method step. Thus, the claims, given their broadest reasonable interpretation (i.e., as claims are to be examined), are interpreted as a source comprising a polymer in which a nuclide which is "activatable" is in the chain. Such activatable nuclides include various atoms, including carbon. Eury disclose a integral source comprising a polymer having carbon in the chain, e.g., polyurethane, etc., see col. 4, lines 26, etc. The term "activatable" is a "capable of" only requires the ability to so perform, see *In re Hutinson*, 69 USP 138, but does not differentiate over the prior art by necessitating some type of method step into the claims. Since applicant states that carbon is such a nuclide, then the polymers which have carbon in the chain as disclosed by the prior art would have a nuclide that is activatable. The same nuclide, carbon (as claimed) cannot have different properties as compared to the carbon in the polymer chain of the prior art. The products disclosed by Eury include enclosures which are both flexible, hydrogels or rigid, stents, etc., see column 4.

It is noted that the newly added claims do not differentiate over the cited prior art since the prior art discloses products which may have radioactive wall of a flexible or rigid material. Also, the limitations of claim 5 do not differentiate because there is not limitation on the size of the checkerboard or how the active and inactive squares are differentiated.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Suthanthiran (US 5,163,896) or Eury (US 5,871,436) in view of either one of Park (US 6,152,869) or Good (US 5,342,283), for the reasons set forth in the office action mailed 4/22/2002.

Applicant's arguments filed 10/28/2002 have been fully considered but they are not persuasive.

Applicant repeats the arguments that the primary references fail to disclose a nuclide that is chemically bound constituent of a polymer chain and/or which is activatable.

This is not found persuasive because "activatable" is not a positive recitation and only requires the ability to so perform. Applicant defines "activatable" nuclides to include carbon. The prior art disclosed radioactive sources comprising a polymer in which carbon is part of the chain, thus, has all the limitations of the polymer as claimed. The prior art also has the same intended use, as a radioactive enclosure, as claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1 and 3-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/506,611.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the both set of claims are drawn to overlapping devices listed in Markush format. It would have been obvious to one of ordinary skill in the art to form any of the devices as claimed in both applications using the integral source, which would arrive at the same invention as the copending application (e.g., same devices having the same components).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "minature" in claim 5 is a relative term which renders the claim indefinite. The term "minature" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Also, the recitation of claim 5 because it is unclear what is meant by "active" and "inactive" squares, what is meant by target nuclides or what constitutes the checkerboard, e.g., what differentiation is required, what size of the squares, etc. It is unclear how the limitations in claim 5 further define the integral source of claim 1.

Conclusion

No claims are allowable at this time.

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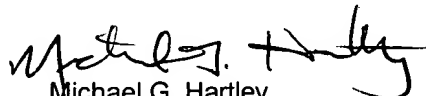
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
December 10, 2002